

SEP 18 2002

K020581

510(k) Summary of Safety and Effectiveness

**Manufacturer:** Medical Concepts Development

2500 Ventura Drive  
Woodbury, MN 55125  
Fax: 651-735-7197  
Phone: 800-345-0644

**Date prepared:** 7/25/02

**Contact:**

**Classification:** Class II, *ColoShield Colonoscopy Drape Model E2000*

**Predicate Device:** 3M™ Steri-Drape™ 1100

**Device Description:** The proposed surgical drape is composed of polyethylene film and polypropylene components. The drape is a blue polyethylene sheet with an acrylic copolymer adhesive. The drape has a fluid collection pouch. The middle of the drape has a polypropylene ring approximately 5.25" in diameter. It is used to hold in place a polypropylene plate that reduces the 6.25" diameter down to 1.70" in diameter. The polypropylene plate has a thermo-plastic elastomer (TPE) feature that is molded to the 1.70" polypropylene plate aperture with a 0.375" diameter fenestration that secures around an endoscope. Attached to the bottom of the plate is a polyethylene reservoir. This reservoir may be used to contain a water-soluble lubricant to aid in the insertion of the scope during the procedure.

**Intended use:**

Use the ColoSHIELD during colonoscopy procedures to protect the clinical staff from patient secretions and to help maintain a cleaner procedural site.

**Substantial Equivalence:** The intended use is the same as the predicate device

**Summary of testing:**

The adhesive component of the drape was evaluated per the applicable section of ISO 10993-1 for skin contact devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

SEP 18 2002

Mr. Eric Euteneuer  
Medical Concepts Development, Incorporated  
2500 Ventura Drive  
Woodbury, Minnesota 55125-3927

Re: K020581  
Trade/Device Name: ColoSHIELD Colonoscopy Drape  
Regulation Number: 878.4370  
Regulation Name: Surgical Drapes and Drape Accessories  
Regulatory Class: II  
Product Code: KKK  
Dated: June 28, 2002  
Received: July 1, 2002

Dear Mr. Euteneuer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

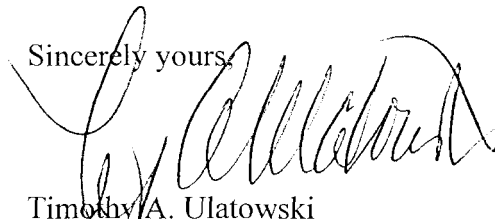
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Timothy A. Ulatowski  
Director

Division of Anesthesiology, General Hospital,  
Infection Control and Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) number (if known): K020581

Device name: ColoSHIELD Colonoscopy Drape

Indications for Use:

Use the ColoSHIELD during colonoscopy procedures to protect the clinical staff from patient secretions and to help maintain a cleaner procedural site.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH; Office of Device Evaluation (ODE)

Chin S. Lin

(Division Sign-Off)  
Division of Anesthesiology, General Hospital,  
Infection Control, Dental Devices

510(k) Number: K020581